REMARKS

This Amendment, filed in reply to the Office Action dated January 25, 2010, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1, 3-23 and 25-30 are all the claims pending in this application. Claims 7-23 and 28-30 are withdrawn from consideration. Claims 1, 3-6 and 25-27 are rejected. Claims 25-27 are canceled herewith without prejudice or disclaimer.

No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

Information Disclosure Statement

Applicants thank the Examiner for returning a signed and initialed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed August 20, 2009.

I. The Rejection of Claims 25-27 Under 35 U.S.C. § 112 is Moot

On page 2 of the Office Action, Claims 25-27 are newly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Solely to advance prosecution, Claims 25-27 are canceled herewith, mooting this rejection. Applicants respectfully request withdrawal of the rejection.

II. The Rejection of Claims 25-27 Under 35 U.S.C. § 102 is Moot

On page 3 of the Office Action, Claims 25-27 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Ransohoff *et al.* (U.S. Patent Application Publication

2003/0176660)("Ransohoff"). Solely to advance prosecution, Claims 25-27 are canceled herewith, mooting this rejection. Applicants respectfully request withdrawal of the rejection.

III. Claims 1 and 3-6 are Patentable Under 35 U.S.C. § 103

On page 6 of the Office Action, Claims 1 and 3-6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sang *et al.* (U.S. Patent Application Publication 2005/0273872)("Sang"), as evidenced by Kamachi *et al.* (Development 125:2521-2532; 1998)("Kamachi"), in view of Rapp, J. (U.S. Patent Publication No. 2002/0108132)("Rapp") for reasons of record. For brevity, these reasons are not reiterated herein.

Applicants' arguments that the developmental stages of chicken embryos in Sang and Kamachi are different from each other and thus fail to teach infection at least 24 hours after the start of incubation, was not found persuasive. In particular, the Office Action states that the developmental stages in Sang as defined according to Eyal-Giladi, which refers to further refinement of earlier developmental stages does not negate or preclude the established and accepted stages in chick development. The Examiner further states that the Abstract of Eyal-Giladi concludes by suggesting that the term germ may be used for all early stages, and the term blastoderm is applied from stage VI onward. The Office Action concludes that a person of ordinary skill in the art reading Eyal-Giladi as a whole would not ignore the established developmental stages of chick development. Furthermore, the Examiner, relying on Experiment 2, paragraph [0065] of Sang *et al,* states that the blastoderm must necessarily be at stage VI and beyond.

Applicants respectfully disagree. In response, Applicants hereby clarify the difference between the developmental stages as defined according to Hamburger and Hamilton (1951) in

Kamachi (see page 2524, 2nd paragraph, right column of Kamachi), and the developmental stages in Sang as defined according to Eyal-Giladi & Kochav (1976) (see [0064] of Sang). In particular, the staging of chicken embryos in Hamburger and Hamilton (Kamachi) and Eyal-Giladi & Kochav (Sang) are different from each other in that Stage XIII of Sang does not correlate to Stage 13 in Kimachi. Sang describes chick embryos at developmental stages X-XIII, classified according to the Eyal-Giladi and Kochav staging description. On the other hand, Kamachi describes on page 2524, right column, that chicken embryos are staged based on somite numbers according to Hamburger and Hamilton staging. The abstract of Eyal-Giladi and Kochav describes studying chick embryos at Stages I-XIV, which precedes stage 2 of Hamburger and Hamilton. *See also* Journal of Morphology Vol. 88, Na. 1 49-92(1931 print, 1951). Therefore, stage XIII in Eyal-Giladi and Kochav corresponds to the period before stage 2 in Hamburger and Hamilton. As expressly stated in Hamburger and Hamilton, *A series of Normal Stages in the Development of the Chick Embryo*, pages 54 and 56 (previously submitted), stage 2 is usually obtained after 6-7 hours of incubation and stage 13 is usually obtained after 48-52 hours of incubation. Therefore, contrary to the Examiner's assertions, the developmental stages described in Sang are distinct from Kamachi.

None of the cited reference teach or suggest the claimed invention. In particular, Sang fails to disclose or suggest virus infection of the embryo that occurs "at least 24 hours after the start of incubation," as presently claimed. As mentioned above, Hamburger and Hamilton defines stage XIV to be stage 2, and stage 2 is reached by 7 hours of incubation. As such, the infection of Sang, which occurs at stages X-XIII, occurs prior to even 7 hours of incubation. At no point does Sang disclose or suggest initiating infection after 7 hours of incubation. In contrast, the present claims recite that infection is performed at least 24 hours after the start of

incubation, which is later than the infection of Sang by more than 3-fold. Thus, because Sang explicitly discloses that virus infection is performed 7 hours after the start of the incubation, at the latest, one of ordinary skill in the art would not have been motivated to try to initiate infection at least 24 hours after the start of incubation, as claimed. Rapp fails to cure the deficiencies of Sang.

Furthermore, Applicants note that unexpected results is evidence of the nonobviousness of the claimed invention. As MPEP § 716.02(a) states, "[e]vidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. 'Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness.' ... *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987) ... [p]resence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)." Applicants submit that by performing the transfection at the specific time period (at least 24 hours after the start of incubation, as presently claimed), the birds so obtained avoid gene silencing, resulting in the efficient expression of exogenous antibody. In particular, Figures 1 and 2, illustrated below, depict the results of the relationship between the period of the transfection and the expression of β -galactosidase as a transgene in G0 transgenic birds.

Fig. 1

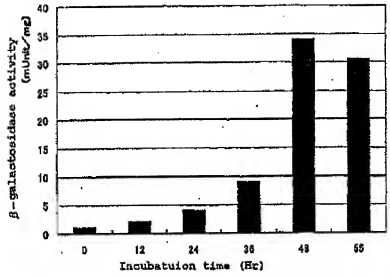
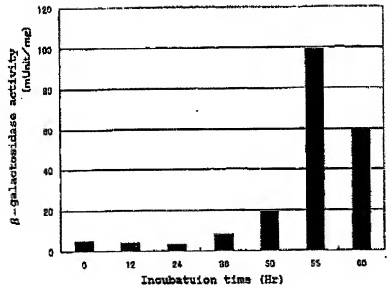


Fig. 2



In the experiments from which the results are depicted above, transfection is performed using the same retroviral vector as in the present invention, except that β-galactosidase was employed as a reporter transgene. Figure 1 depicts the expression of β -galactosidase in quail,

and Figure 2 depicts the expression of β -galactosidase in chicken. As would be clear to those of ordinary skill in the art, transfection at 0 or 12 hours post-incubation results in poor transgene expression. However, when transfection is performed 24 hours post-incubation, or later, expression of β -galactosidase markedly increases. Those of ordinary skill in the art would not have expected or predicted that performing the transfection at least 24 hours after the start of incubation would produce such a marked increase in transgene expression.

For the foregoing reasons, neither Sang nor Rapp disclose or suggest the claimed transgenic bird, wherein the early embryo is infected with the claimed retroviral vector at least 24 hours after the start of incubation. Accordingly, Sang nor Rapp, taken alone or in combination, do not teach each and every element of Claim 1. For these same reasons, Claims 3-6 are not rendered obvious by the cited references.

Reconsideration and withdrawal of the rejection under § 103(a) is respectfully requested.

2. On page 11 of the Office Action, the Examiner reinstates the rejection of Claims 1 and 3-6 under 35 U.S.C. 102(e) as allegedly being anticipated by Sang, as evidenced by Kamachi, as previously set forth in the Office Action dated March 19, 2008. In particular, the Examiner states that since Applicants have amended base Claim 1 to remove the limitation: "wherein the replication-deficient retroviral vector is derived from Moloney murine leukemia virus," the rejection has been reinstated.

As discussed above in response to the rejection under 35 U.S.C. § 103, Sang fails to expressly or inherently teach the limitation "wherein the early embryo is at least 24 hours after the start of incubation." To the contrary, Sang teaches that infection occurs at stages X-XIII, which is significantly earlier than 7 hours post-incubation. In contrast, infection in the present invention is performed at least 24 hours after the start of incubation, which is later than the

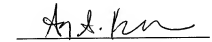
infection of Sang by more than 3-fold. Since Sang fails to disclose each and every element of the claimed invention, either expressly or inherently, anticipation is improper. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir 1987)("[a] claim is anticipated *only* if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Applicants respectfully request withdrawal of the rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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